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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,215	10/16/2001	Janice K. Albrecht	IN01344	5760

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,215	ALBRECHT, JANICE K.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/17/3*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Raw sequence listing error report.

DETAILED ACTION

In the paper submitted November 17, 2003, applicant amended claim 9. Claims 1-42 are pending and under consideration. Upon further consideration, new grounds of rejection are required.

Terminal Disclaimer

The terminal disclaimer filed on November 17, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,472,373 and 6,172,046 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 13, 15, 17, 19, 20, 29 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 13, 15, 17, 19, 29 and 33 recite "at least about". It is unclear what is intended by this range recited in claims 11, 13, 15, 17, 19 and 29 since 12 mg/kg would be "about" 13 mg/kg, but 12 mg/kg would not be "at least". Claim 33 also recites this same language, "at least about" in reference to weeks. Again, 23 weeks would be "about" 24, but 23 would not be "at least" 24. Claim 20 recites "greater than about" and "less than about" when referring to a patient's weight. It cannot be determined what weight is encompassed by "greater" or "less than about".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4, 13-15, 19-24, 26-30, 32-35 and 37-39 of U.S. pre-grant publication no. US 2003/0055013 . Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are drawn to a method of treating HCV by administering a weight-effective amount of ribavirin ranging from 800-1400 mg/day and a weight-effective amount of pegylated interferon alfa ranging from 1.5 μg/kg. The instant claims are anticipated by the claims of US 2003/0055013 because the same dose ranges are administered for the same length of time in a method to treat any form of HCV, regardless of viral titer. The dose range of ribavirin administered anticipates the weight-effective amounts instantly claimed.

Claims 1-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. pre-grant publication no. US 2002/0119122 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because Stalgis et al. anticipate a method of treating HCV

genotypes 1, 2 and 3 with 400-1600 mg per day of ribavirin and 0.5-1.5 μg/kg of pegylated interferon alfa, see claims 1-36. The dose range of ribavirin administered anticipates the weight-effective amounts instantly claimed.

Claims 1-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-70 of U.S. pre-grant publication no. US 2003/0039630 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because Albrecht anticipate a method of treating HCV genotypes 1, 2 and 3 with 400-1600 mg per day of ribavirin and 0.5-1.5 μg/kg of pegylated interferon alfa, see claims 1-70. The dose range of ribavirin administered anticipates the weight-effective amounts instantly claimed.

Claims 1-3, 7, 8, 11, 20 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-7 of U.S. pre-grant publication no. US 2002/0055473. Although the conflicting claims are not identical, they are not patentably distinct from each other because Ganguly et al. claim a method of using a therapeutically effective amount of ribavirin and a therapeutically effective amount of an interferon alfa, such as 0.5 to 2.0 μg/kg of pegylated interferon alfa to treat chronic hepatitis C infections. Ganguly et al. define a therapeutically effective amount of ribavirin as 200 to 1600 mg per day. These teachings anticipate the instant claims.

Claims 1-3, 7, 8, 11, 20 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 21, 32 and 42 of U.S. pre-grant publication no. US 2003/0004119. Although the conflicting claims are not identical, they are not patentably distinct from each other because Ganguly et al. claim a method

of treating a chronically infected HCV patient by administering an effective amount of a ribavirin derivative and an effective amount of interferon alfa. Ganguly et al. define an effective amount as 200 to 1600 mg per day of ribavirin and 0.1 to 9.0 μg/kg of pegylated interferon alfa, see paragraph 0153-0157. Administering ribavirin would have been an obvious alternative to administering the ribavirin derivative of Ganguly et al. because administration of ribavirin to treat HCV is a conventional therapy in the art.

The rejections above are provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 7, 8, 11, 20 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13 and 22-28 of U.S. Patent No. 6,635,646. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treating HCV with weight effective amounts of ribavirin and pegylated interferon is anticipated by US 6,635,646.

Claims 1-3, 7, 8, 11, 20 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38 of U.S. Patent No. 6,673,775. Although the conflicting claims are not identical, they are not patentably distinct from each other because Ganguly et al. claim a method of treating a patient infected with HCV by administering a therapeutically effective amount of a ribavirin derivative and an effective amount of an interferon alfa for a time sufficient to eradicate HCV-RNA levels, see claim 38. Ganguly et al. define a therapeutically effective amount of the ribavirin derivative as ranging between 200-1600 mg/day and the therapeutically effective amount of pegylated interferon, which is an interferon alfa, as ranging between 0.25-1.5 μg/kg, see column 25, line 7 to column

26, line 38. Administering ribavirin would have been an obvious alternative to administering the ribavirin derivative of Ganguly et al. because administration of ribavirin to treat HCV is a conventional therapy in the art.

Claims 1-3, 7, 8, 11, 20 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,403,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because Ganguly et al. claim a method of treating a patient infected with HCV by administering a therapeutically effective amount of a ribavirin derivative and an effective amount of an interferon alfa for a time sufficient to eradicate HCV-RNA levels, see claim 2. Ganguly et al. define a therapeutically effective amount of the ribavirin derivative as ranging between 200-1600 mg/day and the therapeutically effective amount of pegylated interferon, which is an interferon alfa, as ranging between 0.25-1.5 μg/kg, see column 20, line 65 to column 22, line 29. Administering ribavirin would have been an obvious alternative to administering the ribavirin derivative of Ganguly et al. because administration of ribavirin to treat HCV is a conventional therapy in the art.

Claims 1-3, 7, 8, 11, 20 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 28, 35 and 36 of U.S. Patent No. 6,277,830. Although the conflicting claims are not identical, they are not patentably distinct from each other because Ganguly et al. claim a method of treating a chronically infected HCV patient by administering an effective amount of a ribavirin derivative and an effective amount of interferon alfa for a time sufficient to eradicate detectable HCV-RNA levels. The interferon alfa administered is pegylated, see claims 16, 28, 35 and 36. Ganguly et al. define an

effective amount as 200 to 1600 mg per day of ribavirin and 0.1 to 9.0 μg/kg of pegylated interferon alfa, see column 4, line 50 to column 5, line 57. Administering ribavirin would have been an obvious alternative to administering the ribavirin derivative of Ganguly et al. because administration of ribavirin to treat HCV is a conventional therapy in the art.

Claims 1-3, 7, 8, 11, 20 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,387,365 B1 in view of Gilbert (WO 95/13090).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the respective methods recite overlapping dose ranges. Other respective variations include optimization with pegylated interferon.

Gilbert et al. disclose that pegylated forms of interferon alpha retain all of the biological activity as the unconjugated forms, and are longer acting, see page 12.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use the pegylated interferon of Gilbert in the method of Albrecht et al. to increase the duration of activity. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for substituting a pegylated form for non-pegylated form because the functional activity is the same.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Glue et al. (WO 00/37110).

See the summary of the claims above.

Glue et al. anticipate a method of treating different HCV genotypes by administering 400-1600 of ribavirin a day and 0.5 to 1.5 μg/kg of pegylated interferon alfa for the same treatment time period to eradicate HCV-RNA levels, see claims 1-25.

Claims 1-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Glue et al. (Hepatology. September 2000; 32 (3): 647-53).

See the summary of the claims above.

Glue et al. anticipate treating chronic HCV by administering 1.4 μg/kg of pegylated interferon alfa and 600-1200 mg/kg of ribavirin to eradicate detectable levels of HCV RNA, see the entire reference.

Claims 1-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Stalgis et al. (US Pre-grant application (US 2002/0119122 A1).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

See the summary of the claims above.

Stalgis et al. anticipate a method of treating HCV genotypes 1, 2 and 3 with 400-1600 mg per day of ribavirin and 0.5-1.5 μg/kg of pegylated interferon alfa, see claims 1-36. The dose range of ribavirin administered anticipates the weight-effective amounts instantly claimed.

Claims 1-3, 7, 8, 11, 20 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Laughlin (US 6,635,646).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-3, 7, 8, 11, 20 and 29 are drawn to a method of treating HCV by administering a weight-effective amount of ribavirin (800-1400 mg/day) and a weigh-effective amount of pegylated interferon (about 1.5 μg/kg).

Laughlin anticipate a method of treating HCV by administering 8-15 mg/kg per day of ribavirin and 0.1-9.0 μg/kg of pegylated interferon, see claims 13 and 22-28.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (reference AN provided in the IDS) and Gilbert (WO 95/13090).

See the summary of the claims above.

Davis et al. teach treating chronic HCV by administering 1000 or 1200 mg per day of ribavirin, depending on body weight, and 3 million units of interferon three times a week. Davis et al. do not teach administering pegylated interferon. Although the dose of interferon administered by Davis et al. is in different units, the amount administered in the reference is equivalent to the species within the range claimed. Further, it is conventional practice in the vaccine art to optimize dosages, depending on individual factors for each patient.

Gilbert et al. disclose that pegylated forms of interferon alpha retain all of the biological activity as the unconjugated forms, and are longer acting, see page 12.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use the pegylated interferon of Gilbert in the method of Davis et al. to increase the duration of activity. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for substituting a pegylated form for non-pegylated form because the functional activity is the same.

Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over McHutchison et al. (reference AM of the IDS) and Gilbert (WO 95/13090).

See the summary of the claims above.

McHutchison et al. teach treating chronic HCV by administering 1000 or 1200 mg per day of ribavirin, depending on body weight, and 3 million units of interferon three times a week. McHutchison et al. do not teach administering pegylated interferon. Although the dose of

interferon administered by McHutchison et al. is in different units, McHutchison et al. teach that the dose is a standard amount administered. In addition, the amount administered by McHutchison et al. is equivalent to the species within the range claimed. Further, it is conventional practice in the vaccine art to optimize dosages, depending on individual factors for each patient. McHutchison et al. do not teach pegylated interferon.

Gilbert et al. disclose that pegylated forms of interferon alpha retain all of the biological activity as the unconjugated forms, and are longer acting, see page 12.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use the pegylated interferon of Gilbert in the method of McHutchison et al. to increase the duration of activity. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for substituting a pegylated form for non-pegylated form because the functional activity is the same.

Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poynard et al. (provided in the IDS as AL) and Gilbert (WO 95/13090).

See the summary of the claims above.

Poynard et al. teach treating chronic HCV by administering 1000 or 1200 mg per day of ribavirin and 3 million units of interferon three times a week. Poynard et al. do not teach administering pegylated interferon. Although the dose of interferon administered by Poynard et al. is in different units, the amount administered by Poynard et al. is equivalent to the species within the range claimed. Further, it is conventional practice in the vaccine art to optimize dosages, depending on individual factors for each patient. Poynard et al. do not teach pegylated interferon.

Gilbert et al. disclose that pegylated forms of interferon alpha retain all of the biological activity as the unconjugated forms, and are longer acting, see page 12.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use the pegylated interferon of Gilbert in the method of Poynard et al. to increase the duration of activity. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for substituting a pegylated form for non-pegylated form because the functional activity is the same.

Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reichard et al. (provided in the IDS as AK) and Gilbert (WO 95/13090).

See the summary of the claims above.

Reichard et al. teach treating chronic HCV by administering 1000 or 1200 mg per day of ribavirin and 3 million units of interferon three times a week. Reichard et al. do not teach administering pegylated interferon. Although the dose of interferon administered by Reichard et al. is in different units, the amount administered by Reichard et al. is equivalent to the species within the range claimed. Further, it is conventional practice in the vaccine art to optimize dosages, depending on individual factors for each patient. Reichard et al. do not teach pegylated interferon.

Gilbert et al. disclose that pegylated forms of interferon alpha retain all of the biological activity as the unconjugated forms, and are longer acting, see page 12.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use the pegylated interferon of Gilbert in the method of Reichard et al. to increase the duration of activity. One of ordinary skill in the art at the time the invention was

made would have had a reasonable expectation of success for substituting a pegylated form for non-pegylated form because the functional activity is the same.

The applied references of US 6,403,564 and US 6,277,830 have a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1-3, 7, 8, 11, 20 and 29 are rejected under 35 U.S.C. 103(a) as being obvious over Ganguly et al. (US 6,403,564).

Ganguly et al. claim a method of treating a patient infected with HCV by administering a therapeutically effective amount of a ribavirin derivative and an effective amount of an interferon alfa for a time sufficient to eradicate HCV-RNA levels, see claim 2. Ganguly et al.

define a therapeutically effective amount of the ribavirin derivative as ranging between 200-1600 mg/day and the therapeutically effective amount of pegylated interferon, which is an interferon alfa, as ranging between 0.25-1.5 μg/kg, see column 20, line 65 to column 22, line 29. Administering ribavirin would have been an obvious alternative to administering the ribavirin derivative of Ganguly et al. because administration of ribavirin to treat HCV is a conventional therapy in the art.

Claims 1-3, 7, 8, 11, 20 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly et al. US (6,277,830).

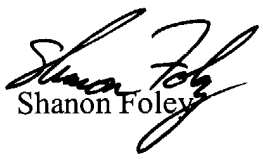
Ganguly et al. claim a method of treating a chronically infected HCV patient by administering an effective amount of a ribavirin derivative and an effective amount of interferon alfa for a time sufficient to eradicate detectable HCV-RNA levels. The interferon alfa administered is pegylated, see claims 16, 28, 35 and 36. Ganguly et al. define an effective amount as 200 to 1600 mg per day of ribavirin and 0.1 to 9.0 μg/kg of pegylated interferon alfa, see column 4, line 50 to column 5, line 57. Administering ribavirin would have been an obvious alternative to administering the ribavirin derivative of Ganguly et al. because administration of ribavirin to treat HCV is a conventional therapy in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley